UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/818,228	03/27/01	CHRISTOPHER K	1246/39(A)

QM32/1005
THOMAS S. BIRNEY, ESQ.
DORR, CARSON, SLOAN & BIRNEY, P.C.
3010 E. 6TH AVENUE
DENVER CO 80206

EXAMINER	
PATEL, M	
ART UNIT	PAPER NUMBER
3761	3

DATE MAILED: 10/05/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

1- File Copy

Office Action Summary	Application No.	Applicant(s)	
	09/818,228	CHRISTOPHER, KENT L.	
	Examiner	Art Unit	
	Mital B. Patel	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 March 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *2* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Claim Rejections - 35 USC § 101

1. Claims 1-22 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claims 1 and 15 positively recite a part of the human body. In Claims 1 and 15, "...**a distal end extending through a patient's nose and into the patient's distal nasopharynx or oropharynx; a delivery tube extending below the patient's nostril connected to the proximal end of the nasal catheter**;...." The following language is suggested: -- a distal end **adapted to extend** through a patient's nose and into the patient's distal nasopharynx or oropharynx; a delivery tube **adapted to extend** below the patient's nostril--.

Claim Rejections - 35 USC § 103

2. Claims 1-4, 8, 11-17, 19, 20, 23, and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brekke (3915173).

3. As to claim 1, Brekke teaches a nasopharyngeal catheter comprising a nasal catheter **44** having a proximal end and a distal end adapted to extend through a patient's nose and into the patient's distal nasopharynx or oropharynx; a delivery tube **26** connected to the proximal end of the nasal catheter; and a gas source. It should be noted that Brekke fails to specifically teach a delivery tube adapted to extend below the patient's nostril. However, the use of such a delivery tube is well known in the art and modification of Brekke's delivery tube to the recited delivery tube would well be within the scope of one of ordinary skill in the art. Furthermore, the particulars of the flow rate depend on the individual and intended therapy.

4. As to claim 2, Brekke teaches a nasopharyngeal catheter wherein the nasal catheter comprises a flexible plastic tube that can be cut to a desired length.

5. As to claim 3, the use of a plurality of markings as an indicator is well known in the art.

6. As to claim 4, the use of a radio-opaque strip in a catheter is well known in the art.

7. As to claim 8, the particulars of the dimensions of the catheter can be arrived at through routine observation and experimentation and therefore carry no patentable weight.

8. As to claim 11, the particulars of the back pressure with respect to the gas supplied depends on the intended therapy and also the back pressure can be arrived at through routine observation and experimentation.

9. As to claims 12-14, the particular gases used depends on the intended therapy and therefore carries no patentable weight.

10. As to claim 15, Brekke teaches a nasopharyngeal catheter comprising a nasal catheter **44** having a proximal end and a distal end adapted to extend through a patient's nose and into the patient's distal nasopharynx or oropharynx; the catheter being made of flexible material that can be trimmed to a desired length; a delivery tube **26** connected to the proximal end of the nasal catheter; and a gas source. It should be noted that Brekke fails to specifically teach a delivery tube adapted to extend below the patient's nostril. However, the use of such a delivery tube is well known in the art and modification of Brekke's delivery tube to the recited delivery tube would well be within the scope of one of ordinary skill in the art. Furthermore, the particulars of the flow rate depend on the individual and intended therapy.

11. As to claim 16, the use of a plurality of markings as an indicator is well known in the art.

12. As to claim 17, the use of a radio-opaque strip in a catheter is well known in the art.

13. As to claim 20, the particulars of the dimensions of the catheter can be arrived at through routine observation and experimentation and therefore carry no patentable weight.

14. As to claim 23, Brekke teaches a method for providing a supplemental flow of air/oxygen to a spontaneously breathing patient, the method comprising advancing a nasopharyngeal catheter through a patient's nostril until the distal tip of the catheter is located in the patient's distal nasopharynx or oropharynx. It should be noted that Brekke fails to specifically teach the step of supplying air/oxygen through the catheter at a flow rate of approximately 4 to 40 liters per minute. However, in performing this method of supplying air/oxygen there would be a flow rate that would fall within the range of 4- 40 liters.

15. As to claim 24, Brekke teaches essentially all of the limitations except providing a delivery tube extending beneath the patient's nostril for delivering the flow of air/oxygen, the delivery tube having a connecter for attachment to the catheter; however, providing such a delivery tube is known in the art. Brekke also fails to teach the step of cutting the proximal end of the catheter to a desired length so that the distal tip of the catheter will have a desired position relative to the patient's uvula. However, it would be obvious to one of ordinary skill in the art to cut the proximal end of the catheter depending on the individual the catheter is to be inserted into.

16. As to claim 25, Brekke teaches essentially all of the limitations except for the initial step of selecting the length of the catheter by advancing a catheter through a patient's nostril until the distal tip of the catheter is visible through the patient's mouth below the patient's uvula. However, it would be obvious to one of ordinary skill in the art to include this initial step since the length of the catheter will differ from individual to individual.

17. As to claim 26, the method of supplying helium is known in the art.

18. Claims 5, 6, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brekke in view of Dali et al (3682171).

19. As to claim 5, Brekke teaches a nasopharyngeal catheter wherein the delivery tube further comprises two opposing ends with connectors for removable attachment to the gas source. Brekke fails to specifically teach a cap removably insertable into a connector that is not attached to the gas source. However, Dali et al. does teach a cap (plug) removably insertable into a connector that is not attached to the gas source. Therefore, it would be obvious to one of ordinary skill in the art to include of the cap of Dali et al. in Brekke's catheter to cap the connector when it is not in use to prevent it from collecting dust and bacteria in the connector and causing contamination.

20. As to claim 6, Brekke fails to specifically teach a connector for removably attaching the proximal end of the nasal catheter to the delivery tube. However, it would be obvious to one of ordinary skill in the art to provide such a connector in Brekke so that if the pieces needed to be cleaned or replaced it would be easy to do so without having to discard the entire device.

21. As to claim 18, Brekke teaches a nasopharyngeal catheter wherein the delivery tube further comprises two opposing ends with connectors for removable attachment to the gas source. Brekke fails to specifically teach a cap removably insertable into a connector that is not attached to the gas source. However, Dali et al. does teach a cap (plug) removably insertable into a connector that is not attached to the gas source. Therefore, it would be obvious to one of ordinary skill in the art to include of the cap of Dali et al. in Brekke's catheter to cap the

connector when it is not in use to prevent it from collecting dust and bacteria in the connector and causing contamination.

22. Claims 7 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brekke in view of Spofford et al (5297546).

23. As to claim 7, Brekke teaches a nasal catheter having essentially all of the claimed limitations except for the catheter comprising a hydrophilic coating. Spofford et al teaches a catheter comprising a hydrophilic coating for limiting adhesion and subsequent build-up of mucous-type materials which would restrict the flow of oxygen through the catheter. Therefore, it would be obvious to one of ordinary skill in the art to modify Brekke's catheter to have a hydrophilic coating for limiting adhesion and subsequent build-up of mucous-type materials which would restrict the flow of oxygen through the catheter.

24. As to claim 19, Brekke teaches a nasal catheter having essentially all of the claimed limitations except for the catheter comprising a hydrophilic coating. Spofford et al teaches a catheter comprising a hydrophilic coating for limiting adhesion and subsequent build-up of mucous-type materials which would restrict the flow of oxygen through the catheter. Therefore, it would be obvious to one of ordinary skill in the art to modify Brekke's catheter to have a hydrophilic coating for limiting adhesion and subsequent build-up of mucous-type materials which would restrict the flow of oxygen through the catheter.

25. Claims 9, 10, 21, 22, 26, and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brekke in view of Daniell et al (6050260).

26. As to claim 9, Brekke teaches essentially all of the claimed limitations except for a humidifier controlling the humidity of the gas delivered through the nasal catheter. However,

Daniell does teach a humidifier for humidifying the gases delivered to the patient in order to prevent dehydration of the airways and nasal passages of the patient. Therefore, it would have been to one of ordinary skill in the art to modify Brekke's device to include a humidifier for humidifying the gases delivered to the patient in order to prevent dehydration of the airways and nasal passages of the patient.

27. As to claim 10, the above combination teaches a nasopharyngeal catheter comprising a heater for controlling the temperature of the gas delivered through the catheter.

28. As to claim 21, Brekke teaches essentially all of the claimed limitations except for a humidifier controlling the humidity of the gas delivered through the nasal catheter. However, Daniell does teach a humidifier for humidifying the gases delivered to the patient in order to prevent dehydration of the airways and nasal passages of the patient. Therefore, it would have been to one of ordinary skill in the art to modify Brekke's device to include a humidifier for humidifying the gases delivered to the patient in order to prevent dehydration of the airways and nasal passages of the patient.

29. As to claim 21, the above combination teaches a nasopharyngeal catheter comprising a heater for controlling the temperature of the gas delivered through the catheter.

30. As to claim 26, Brekke teaches essentially all of the limitations except for the method further comprising controlling the humidity of the air/oxygen supplied through the catheter. However, Daniell teaches the method of controlling the humidity of the gas delivered through the nasal catheter in order to prevent dehydration of the airways and nasal passages of the patient. Therefore, it would have been to one of ordinary skill in the art to include the method of

Daniell for humidifying the gases delivered to the patient in order to prevent dehydration of the airways and nasal passages of the patient.

31. As to claim 27, the above combination teaches a method regulating the temperature of air/oxygen supplied through the catheter.

Conclusion

32. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 6082361, US 5791341, US 5623924, US 5562078, US 5437267, US 4949716, US 4829998, US 4819619, US 4150676, US 3915173, and US 3682171.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mital B. Patel whose telephone number is 703-306-5444. The examiner can normally be reached on Monday-Friday (8:00 - 4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Weiss can be reached on 703-308-2702. The fax phone numbers for the organization where this application or proceeding is assigned are 703-306-4520 for regular communications and 703-306-4520 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

mbp
September 28, 2001

John G. Weiss
Supervisory Patent Examiner
Group 3700

Attachment for PTO-948 (Rev. 03/01, or earlier)
6/18/01

The below text replaces the pre-printed text under the heading, "Information on How to Effect Drawing Changes," on the back of the PTO-948 (Rev. 03/01, or earlier) form.

INFORMATION ON HOW TO EFFECT DRAWING CHANGES

1. Correction of Informalities -- 37 CFR 1.85

New corrected drawings must be filed with the changes incorporated therein Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application If this information is provided, it must be placed on the front of each sheet and centered within the top margin If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings **MUST** be filed within the **THREE MONTH** shortened statutory period set for reply in the Notice of Allowability Extensions of time may NOT be obtained under the provisions of 37 CFR 1 136(a) or (b) for filing the corrected drawings after the mailing of a Notice of Allowability . The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson

2. Corrections other than Informalities Noted by Draftsperson on form PTO-948.

All changes to the drawings, other than informalities noted by the Draftsperson, **MUST** be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings **MUST** be approved by the examiner before the application will be allowed No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes

Timing of Corrections

Applicant is required to submit the drawing corrections within the time period set in the attached Office communication See 37 CFR 1 85(a).

Failure to take corrective action within the set period will result in **ABANDONMENT** of the application